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| EXAMINER | |
|---|---|
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/544,260 | BLUNN ET AL. | |
| | Examiner | Art Unit | |
| | JONATHAN STROUD | 3774 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *1-44 and 55-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

The attempt to incorporate subject matter into this application by reference to Bergmann is ineffective because the applicant has failed to include a copy of the cited non-patent literature in the application materials. Further, at the end of the second paragraph on page 1, applicant says "the surgical kit for hemiarthroplasty does not include a reamer or acetabulum.' It is believed that applicant means "prosthetic acetabular cup," but it is unclear. Appropriate correction is required.

### *Claim Objections*

Claim 45 is objected to because of the following informalities: "heniarthroplasty" should be "hemiarthroplasty," and there is no period at the end of step (D). Appropriate correction is required.

### *Response to Arguments*

Applicant's arguments filed 01/102/010 with respect to the rejections have been fully considered but they are not persuasive.

First, applicant is reminded one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues three primary points.

First, applicant contends that nowhere in Ries is a hemiarthroplasty taught, but rather a total hip replacement is taught by that prior art. But Ries is relied on for its disclosure of a variable reamer and the method associated with the variable reaming of a patient's acetabulum – an act long-understood in the art to be involved in both hemiarthroplasty and total hip replacement. In fact, applicant freely admits that it is well known that in hip replacement surgery, either a total hip replacement *or* a hemiarthroplasty can normally be performed. The fact that Ries does not itself disclose the use of the reamer for hemiarthroplasty purposes does not destroy the obviousness of this use, as previously laid out in the prior action. Ries stands for the proposition that variable acetabular reaming is well-known in the prior art in the hip replacement field.

Second, applicant contends that the McGuire reference teaches away from the result desired in the instant application, because it teaches a method of attaching or forming cartilage between an acetabular cup meant for nonarticulation and the underlying reamed acetabulum. However, a reference must be taken for what it teaches to one skilled in the art, not what it individually discloses. In the instant case, the McQuire reference teaches, in pars. 0030-34, the importance of the synovial fluid and the hydrostatic pressure in an articulating surface. The formation of cartilage via pressure and all of these teachings, taken together, suggest the desirability in a hemiarthroplasty of synovial fluid space between the articulating surface to "provide enhanced lubrication" of the surface, para. 0031.

Third, applicant contends that Zaleski does not include any teaching regarding the selection size of a prosethetic implant. This is true. Zaleski is useful because it

teaches that there are surgical parameters measurable, including by way of example body mass index, which can assist a surgeon in a surgical procedure. (abstract.) It is the Ries reference that teaches prosthetic variability, a variable reamer, and a variable joint replacement. The teaching of Zaleski coveys the importance of the patient's biological data and renders obvious the measuring of the patient's characteristics, including at least the body weight. The references teach to one of ordinary skill in the art the method of variably reaming an acetabulum, applying a specific pressure via the synovial fluid present between articulating surfaces, and varying the surgical procedure (the reaming and hence, the size of the prosthetic device) by informed patient data.

As a corollary, it would be helpful to know or disclose what the normal average value for the hydrostatic pressure in a hip joint actually is, and how this relates to applicant's inventive concept.

Taken as a whole, the device of the instant case, as best understood, is obvious to one of ordinary skill in the art for a number of reasons.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for both conventional hip replacement surgery, (see spec., p. 1 ll. 10-15), and a form of hemiarthroplasty (see spec., p. 1 l. 19 and p. 4, l. 4),

it does not reasonably provide enablement for the type of hemiarthroplasty conveyed in the claimed language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to follow and enable the surgical method/invention commensurate in scope with these claims.

"In some cases the hip is repaired by hemiarthroplasty in which the femoral head only is replaced ... however, the acetabulum is left substantially untouched with the natural cartilage still in place. . . . [T]he surgical kit for hemiarthroplasty does not include a reamer or acetabulum (sic)." (spec. p. 1 l. 19.) "... giving a better refined joint than a hemiarthroplasty." (spec. p. 4 l. 4.) This is something contrary to what applicant is claming in the claims. In effect, applicant discloses that a reamer is *not required* for a hemiarthroplasty. Further, there is no clear explanation on how the material characteristics are measured and conveyed to one utilizing the method in the claims.

Further, as best understood (see 112, 2nd paragraph rejection, infra) the hydrostatic pressure as defined in the specification and set forth in the claims appears to be directed to an "average" pressure. However, it is well-known in the art that depending on the state of the joint and the patient's movement, weight, and position, different pressures will exist across the joint. Within the joint, pressure will vary with location. Therefore, it is unclear how the claimed language of "hydrostatic pressure," taken as an average pressure, is enabled in the joint as a whole, or how it would be measured, and when, and in what location, and under what circumstances. Applicant's specification fails to address these deficiencies.

Still further, in embodiments where applicant is adding materials (see dependent claims – such as spacers, membranes, etc) applicant fails to provide any further explanation as to how these spacers may or may not affect the overall hydrostatic pressure. Assuming, as one must given the disclosure, that the pressure is directly related to the force action on a predetermined volume between the two bones of the joint, adding a spacer or membrane would reasonably alter the forces at play and logically, the pressure in the joint space as well. These concerns are not addressed in the description in such a way as to enable the claimed invention.

Accordingly, the amended method claims are not enabled by the specification.

Claims 45-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Similar to the enablement rejection *supra*, the specification discloses a definition for hemiarthroplasty that is contrary to what applicant is attempting to claim in the amended claim 45. Further, due to the lack of the inclusion of non-patent literature in the application materials and a deficiency of explanation, it is unclear how the material values are measured.

Secondly, claims 46 and 47 list a hydrostatic pressure of 2 MPa. However, the specification only supports "more preferably near to 2MPa." (p. 3 l. 34.) There is a lack

of a written description that would reasonably convey that the inventor, at the time the application was filed, had possession of the invention.

Third, as best understood (see 112, 2nd paragraph rejection, infra) the hydrostatic pressure as defined in the specification and set forth in the claims appears to be directed to an "average" pressure. However, it is well-known in the art that depending on the state of the joint and the patient's movement, weight, and position, different pressures will exist across the joint. Within the joint, pressure will vary with location. Therefore there is no written description in the claims that reasonably conveys to one skilled in the art that, at the time of invention, the applicant had possession of the claimed subject matter (as best understood).

Lastly, as noted in the enablement rejection, *supra*, in embodiments where applicant is adding materials (see dependent claims – such as spacers, membranes, etc) applicant fails to provide any further written description as to how these spacers may or may not affect the overall hydrostatic pressure. Assuming, as one must given the disclosure, that the pressure is directly related to the force action on a predetermined volume between the two bones of the joint, adding a spacer or membrane would reasonably alter the forces at play and logically, the pressure in the joint space as well. These concerns are not addressed in the description in such a way as to show that the applicant had possession of the claimed invention, particularly in light of the lack of non patent literature publications, incorporated by reference, that were not provided in the application materials.

Thus, there is not enough written description in the specification to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45-54 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: There is no step to determine the hydrostatic pressure, and it is unclear from the specification exactly how this characteristic will be measured and conveyed. Appropriate correction is required.

Claims 45-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the "hydrostatic pressure" as defined in the specification *appears to be* an average pressure, although it is unclear from the specification. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ries 5,782,928, further in view of McGuire 2005/0202371 further in view of Zaleski 2003/0101076.

Ries 5,782,928 teaches a method of preparing a subject's body for implantation including determining at least one body characteristic, reaming the hip joint's acetabulum, selecting a prosthetic device for implantation corresponding to the at least one body characteristic, and implanting the selected prosthetic device into the space.

Further, since the shapes of the acetabular cups selected are dependent upon the previously determined body characteristics, so too then does it naturally flow that the femoral heads could be similarly selected, independently, based on the information provided.

Ries does not teach leaving a space that specifically allows for 0.5-2 MPa of hydrostatic pressure to accumulate. However, it is likely that this amount of hydrostatic pressure will accumulate at some point in the surgical procedure and/or at some time following – this is a natural results-effective variable in surgical hemiarthroplasty resulting from the articulation of the prosthetic femoral head and the reamed acetabulum surface.

Furthermore, McGuire teaches the desirability and means to create cartilage through body compression and hydrostatic pressures of greater than 0.015MPa, and further, tested in the range of 500-700 kPa (or 0.5-0.7kPa) and higher, pars. [0197-

0200], in order to promote bone and cartilage growth. It further teaches the importance of synovial fluid in articulating surfaces and thus makes the important distinction between the type of pressure-fit and cartilage growth can retard articulation (as necessary for the femoral shaft) and the type of biological conditions - the presence of synovial fluid at similar pressures - which can lead to increased articulation.

Ries in view of McGuire does not explicitly state the step of measuring the patient's body mass or body weight in order to select an appropriate prosthesis.

However, all surgeons know of the importance of patient information in surgical decisions, and generally, patient information is collected prior to surgeries in order to assist the surgeon in decision-making – such as is disclosed in Zaleski 2003/0101076, BMI, patient weight, and other various factors are normally collected and on hand for any surgeon making medical decisions. Therefore, it would be obvious to one of ordinary skill in the art to measure a patient's body weight and use that information to inform the choice of prosthetic device.

Re claims 46 and 47, as best understood (see 112 rejections, *supra),* as stated above, McGuire discloses the desirability of any and all hydrostatic pressures above 0.0015 MPA that do not then damage the tissue, and discloses values of 0.5MPa and up. Applicant's specification supports "preferably close to 2 MPa" and not specifically 2Mpa.

Re claims 48-52, in the current configuration, a spacer element or membrane of cartilage will form *in situ* and be resorbable. Under McGuire's preferred embodiment, a

membrane will be positioned when it forms between the prosthetic femoral head and the acetabular cup, and the acetabular socket.

In the alternative, in a hemiarthroplasty *without* an acetabular cup but employing the teachings of McGuire, a membrane will *always* likewise form (in some fashion and to some extent) between a foreign-body surface and a reamed acetabular socket, even though this effect may be undesirable. The articulation of the joint and the hydrostatic pressure may prevent a further membrane from building up, but in some respect a membrane will form between the femoral head and the inner surface of the acetabular socket for at least a period of time.

Re claim 53, the surface of the prosthetic will deform as taught by McGuire, para. [0009].

Re claim 54, as stated above, but also as taught by Ries, other body characteristics such as the diameter of the reamed socket, the patient's vitals and the dimensions of their body are determined or can be determined.

It would have been obvious to one of ordinary skill in the art to modify Ries in view of McGuire, in order to emphasize the importance of biological conditions including synovial fluid in the hemiarthroplasty articulation, and to teach that exerting direct pressure will lead to cartilage formation, a desirable result in the femoral stem surface of a hemiarthroplasty, and further to modify those in view of Zaleski and the general knowledge of the art, in order to utilize patient's physical and physiological information provided most surgeons in order to make better informed decisions of the choice of prosthetic to be implanted.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on 8-4, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774